



**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

INVENTOR APPLICATION OF: MIAO *et al.*

APPLICATION No.: 09/884,901

FILED: June 18, 2001

FOR: LIVER-SPECIFIC GENE EXPRESSION CASSETTES,  
AND METHODS OF USE

EXAMINER: Burkhart, Michael D.

ART UNIT: 1633

CONF. No: 1704

**Information Disclosure Statement Within Three Months of  
Application Filing or Before First Action – 37 C.F.R. § 1.97(b)**

Mail Stop RCE  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**1. Timing of Submission**

This information disclosure is being filed within three months of the filing date of this application or date of entry into the national stage of an International Application or before the mailing date of a first Office Action on the merits or before the mailing date of a first Office Action on the merits after the filing of a Request for Continued Examination under 37 CFR §1.114, whichever occurs last (37 CFR 1.97(b)(4)). The references listed on the enclosed Form PTO-1449 (modified) may be material to the examination of this application; the Examiner is requested to make them of record in the application.

**2. Cited Information**

☒ Copies of references 1-7 are enclosed.

**3. Effect of Information Disclosure Statement (37 C.F.R. § 1.97(h))**

This Information Disclosure Statement is not to be construed as a representation that: (i) a search has been made; (ii) additional information material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the cited information is, or is considered to be, material to patentability. In addition, applicant does not admit that any enclosed item of information constitutes prior art to the subject invention and specifically reserves the right to demonstrate that any such reference is not prior art.

4. Fee Payment

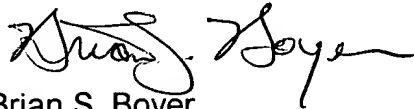
No fees are believed due because this Information Disclosure Statement is being filed before the mailing date of the first Office Action.

However, should the Commissioner determine that fees are due in order for this Information Disclosure Statement to be considered, the Commissioner is hereby authorized to charge such fees to Deposit Account No. 50-2207.

5. Patent Term Adjustment (37 C.F.R. § 1.704(d))

☐ The undersigned states that each item of information submitted herewith was cited in a communication from a foreign patent office in a counterpart application and that this communication was not received by any individual designated in 37 C.F.R. § 1.56(c) more than thirty days prior to the filing of this statement. 37 C.F.R. § 1.704(d).

Respectfully submitted,  
Perkins Coie LLP



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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> Form PTO-1449 (Modified) (Use several sheets if necessary)				<b>COMPLETE IF KNOWN</b>	
				Application Number	09/884,901
				Confirmation Number	1704
				Filing Date	June 18, 2001
				First Named Inventor	Miao et al.
				Group Art Unit	1633
Examiner Name	Burkhart, Michael D.				
Attorney Docket No.	58600-8250				

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U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No.	U.S. Patent or Application		Name of Patentee or Inventor of Cited Document	Date of Publication or Filing Date of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		NUMBER	Kind Code (if known)			

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No.	Foreign Patent or Application			Name of Patentee or Applicant of Cited Document	Date of Publication or Filing Date of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T
		Office	NUMBER	Kind Code (if known)				

OTHER PRIOR ART-NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume issue number(s), publisher, city and/or country where published.	T
	1.	Brinster et al., "Introns increase transcriptional efficiency in transgenic mice". <i>PNAs U.S.A.</i> , 85(3):836-40 (1988).	
	2.	Clayton et al., "Changes in liver-specific compared to common gene transcription during primary culture of mouse hepatocytes", <i>Mol Cell Biol.</i> , 3(9):1552-1561 (1983).	
	3.	Isom et al., "Persistence of liver-specific messenger RNA in cultured hepatocytes: different regulatory events for different genes", <i>J Cell Biol.</i> , 105(6 Pt 2):2877-85 (1987).	
	4.	Kay et al., "Direct Hepatic Gene Delivery in Mice results in Persistent Expression of Human Alpha-1-Antitrypsin <i>in vivo</i> ", <i>Human Gene Therapy</i> , 3:641-647 (1992).	
	5.	Kay et al., "Expression of human alpha-1-antitrypsin in dogs after autologous transplantation of retroviral transduced hepatocytes", <i>PNAs U.S.A.</i> , 89:89-93 (1992).	
	6.	Kay, M.A. et al., "Therapeutic Serum Concentrations of Human Alpha 1-Antitrypsin after Adenoviral-Mediated Gene Transfer into Mouse Hepatocytes", <i>Hepatology</i> , 21:515-519 (1995).	
	7.	Palmiter et al., "Heterologous introns can enhance expression of transgenes in mice", <i>PNAs U S A</i> , 88(2):478-82 (1991).	

EXAMINER	DATE CONSIDERED
*EXAMINER: Initial if reference considered, whether or not criteria is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application(s).	